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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,370	02/19/2002	Marc Alizon	2356-0011-10	2811

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EXAMINER

PARKIN, JEFFREY S

ART UNIT PAPER NUMBER

1648

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/076,370

Applicant(s)

ALIZON ET AL.

Examiner

Jeffrey S. Parkin, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February, and 16 May, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 07/038,330.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Detailed Office Action

Status of the Claims

1. Acknowledgement is hereby made of receipt and entry of the preliminary amendments filed 19 February, and 16 May, 2002, wherein claims 1-22 were canceled without prejudice or disclaimer and new claims 23-30 introduced. Claims 23-30 are currently under examination.

Information Disclosure Statement

2. The information disclosure statement filed 21 June, 2002, has been placed in the application file and the information referred to therein has been considered.

35 U.S.C. § 112, First Paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 23-30 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). *In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one

skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Vas-Cath, Inc., v. Mahurkar*, 935 F.2d at 1563, 19 U.S.P.Q.2d at 1116. The issue raised in this application is whether the original application provides adequate support for the broadly claimed genus of immunogenic polypeptide fragments comprising HIV-1_{MAI} epitopes of 5-150 amino acid residues wherein at least one amino acid residue is substituted in all of the sequences designated HIV-1 BRU, ARV-2, or ELI. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997). The claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence (e.g., epitope) described only by functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the biomolecule of interest. *In re Bell*, 991 F.2d 781, 26 U.S.P.Q.2d 1529 (Fed. Cir. 1993). *In re Deuel*, 51 F.3d 1552, 34 U.S.P.Q.2d 1210 (Fed. Cir. 1995). A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 U.S.P.Q.2d 1895, 1905 (Fed. Cir. 1995). The court noted in this decision that a "laundry list"

disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not reasonably lead those skilled in the art to any particular species.

5 An applicant may show possession of an invention by disclosure of drawings or **structural chemical formulas** that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant
10 was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. For some biomolecules, examples of
15 identifying characteristics include a nucleotide or **amino acid sequence**, chemical structure, **binding affinity**, **binding specificity**, and molecular weight. The written description requirement may be satisfied through disclosure of function and minimal structure when there is a well-established correlation
20 between structure and function. Without such a correlation, the capability to recognize or understand the structure from the mere recitation of function and minimal structure is highly unlikely. In the latter case, **disclosure of function alone is little more than a wish for possession; it does not satisfy the written**
25 **description requirement.** *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566, 43 U.S.P.Q.2d 1398, 1404, 1406 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998). *In re Wilder*, 736 F.2d 1516, 1521, 222 U.S.P.Q. 369, 372-3 (Fed. Cir. 1984). Factors to be considered in determining whether there is
30 sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical

properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention.

Perusal of the disclosure reveals the cloning and characterization of a novel human immunodeficiency virus type 1 originally designated lymphadenopathy associated virus (LAV) MAL, or LAV_{MAL}. A proviral molecular clone was obtained and complete nucleotide isolate of this sequence ascertained (see Figs. 7A-7I). The deduced amino acid sequences of the various viral structural and non-structural genes were also set forth in Figure 7. Specific envelope polypeptide fragments were set forth on p. 36 of the specification (e.g., 1-530, 34-530, 531-877, 680-700, 37-130, 211-289, 488-530, and 490-620). It should be noted that these designations actually referenced LAV_{BRU} amino acid sequences, not specific LAV_{MAL} polypeptides. Thus, the skilled artisan might conclude that applicants contemplated making and using these specific envelope polypeptides. However, the skilled artisan would not reasonably conclude that applicants were in possession of the claimed invention.

First, the disclosure fails to identify specific HIV-1_{MAL} immunogenic fragments of the claimed lengths and substitutions. The specification only sets forth the deduced amino acid sequences of the full-length non-structural and structural genes as set forth in Figure 7 and the specific Env fragments set forth on p. 36. Figure 3 also fails to identify immunogenic MAL peptides. This figure simply provides an amino acid comparison between MAL, BRU, ARV-2, and ELI to assess their genetic relatedness. The figure does not identify or lead the skilled artisan to any particular immunogenic fragment, particularly one carrying amino acid substitutions. Second, the disclosure fails to perform any type of comparison wherein specific immunogenic fragments from isolate MAL are identified and acceptable amino acid substitutions are

performed. It is well-known in the art that subtle perturbations in an amino acid sequence can profoundly affect both the immunogenic and antigenic properties of any given polypeptide. Thus, the skilled artisan can only hazard a guess as to which substituted MAL fragments will remain immunogenic. Third, the disclosure fails to provide adequate support for MAL-specific epitopes of 5-150 amino acid residues. The only numerical limitations set forth in the disclosure are directed toward "hybrid polypeptides" or fusion proteins which may contain between 5 and 150 amino acids (see p. 28). Thus, support does not exist for the current size limitations. Nothing in the disclosure directs the skilled artisan toward any particular MAL immunogenic fragment or any fragment carrying amino acid substitutions. The disclosure fails to identify those molecular determinants modulating the immunogenicity of any given polypeptide fragment. Clearly, the claimed invention simply represents an attempt by applicants to capture subject matter which was neither described nor contemplated at the time of filing. Accordingly, the skilled artisan would reasonably conclude that applicants were not in possession of the claimed invention at the time of filing.

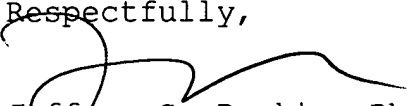
Correspondence

5. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward the following Group 1600 fax number: (703) 872-9306. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227. The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, Laurie Scheiner or James Housel, can be reached at (703) 308-1122 or (703) 308-4027, respectively. Any inquiry of a general nature or relating to the

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Applicants: Alizon, M., et al.

status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Respectfully,



Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

06 September, 2003